



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 1 2004

Heather Crawford, RAC  
Director of Regulatory Affairs  
Vanguard Medical Concepts, Inc  
5307 Great Oak Drive  
LAKELAND FL 33815

Re: K011800 - Supplemental Validation Submission  
Trade/Device Name: See Enclosed List  
Regulation Number: 21 CFR §876.4300  
Regulation Name: Endoscopic electrosurgical unit and accessories  
Regulatory Class: II  
Product Code: NLU  
Dated: September 7, 2001  
Received: September 10, 2001

Dear Ms. Crawford:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on September 10, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

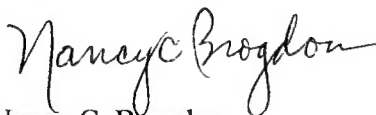
If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## **Attachment 1**

The following list is the models used in this submission.

### **K011800: Vanguard Reprocessed Electric Biopsy Forceps**

Microvasive® Radial Jaw® 3, Model 1550

Bard Precisor, Model 852

Bard Precisor, Model 853

Bard Precisor, Model 854

Bard Precisor, Model 856

K011800

### Indications for Use

510(k) Number: K011800

Device Name: Vanguard Reprocessed Electric Biopsy Forceps

#### Indications for Use:

When used with a compatible electrosurgical unit, endoscope and patient grounding pad, electric biopsy forceps are intended for electrocautery and removal of polyps and/or tissue within the gastrointestinal tract. The forceps are prescription devices intended for a single patient use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K011800

**510(k) Summary of Safety & Effectiveness**

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<b>Submitter</b>	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
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<b>Contact</b>	Mike Sammon, Ph.D. Director, Research & Development (863) 683-8680, extension 228 mikes@safe-reuse.com
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<b>Date</b>	May 31, 2001
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<b>Devices</b>	<ul style="list-style-type: none"><li>• Trade Names: Vanguard Reprocessed Electric Biopsy Forceps ⇒ Boston Scientific Microvasive® Radial Jaw® 3, and ⇒ C.R. Bard Precisor® Electric Biopsy Forceps</li><li>• Common Name: Electric biopsy forceps</li><li>• Classification: 21 CFR 876.4300 – Endoscopic Electrosurgical Unit and Accessories – Class II</li><li>• Product Code KGE</li></ul>
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<b>Predicate Devices</b>	<ul style="list-style-type: none"><li>• Boston Scientific Microvasive® Radial Jaw® 3 Electric Biopsy Forceps believed to be legally marketed under 510(k) premarket notification <u>K860366</u></li><li>• C.R. Bard Precisor® Hot Biopsy Forceps believed to be legally marketed under 510(k) premarket notification <u>K912601</u></li></ul>
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<b>Indications for Use</b>	When used with a compatible electrosurgical unit, endoscope and patient grounding pad, electric biopsy forceps are intended for electrocautery and removal of polyps and/or tissue within the gastrointestinal tract. The forceps are prescription devices intended for a single patient use only.
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## 510(k) Summary of Safety & Effectiveness, Continued

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**Device Description**

Biopsy forceps are devices used to collect tissue samples and/or remove polyps within the gastrointestinal tract via the operating channel of endoscopic instruments.

Electric biopsy forceps include an electrocautery function when used with a compatible electrosurgical unit.

The devices consist of flexible, electrically isolated sheaths with distal grasping cups that are controlled by a proximal handle. The forceps are guided by endoscopy through a biopsy channel with a minimum dimension of 2.8 mm. Monopolar electrocautery requires electrical connection of the forceps to a compatible electrosurgical unit and use of an appropriate patient grounding pad.

Vanguard receives previously used electric biopsy forceps from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the forceps; and returns them to the healthcare facility.

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**Technological Characteristics**

The technological characteristics of the Vanguard reprocessed electric biopsy forceps are the same as the predicate devices, the original equipment manufacturer (OEM) electric biopsy forceps. The materials and dimensions are unchanged and the physical characteristics, performance specifications, and all other characteristics are essentially identical.

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**Test Data**

Decontamination and cleaning, packaging and sterilization validations and functional/performance, shelf life and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

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**Conclusion**

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed electric biopsy forceps are substantially equivalent to the predicate device, the respective OEM biopsy forceps under the Federal Food, Drug and Cosmetic Act.

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